DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 17, 2016

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K080470
Trade/Device Name: RotaFlow Centrifugal Pump System with Bioline Coating
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller Type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: August 29, 2008
Received: September 4, 2008

Dear Ms. Schwenkglenks:

This letter corrects our substantially equivalent letter of September 12, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric E. Richardson -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K080470

Device Name

ROTAFLOW Centrifugal Pump with BIOLINE Coating

Indications for Use *(Describe)*

The Rotaflow Centrifugal Pump is a device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
• Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
• Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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MAQUET

Special 510(k): Device Modification: RotaFlow Centrifugal Pump with Bioline Coating

510(k) SUMMARY

SUBMITTER:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Katrin Schwenkglenks Phone: (011) 49 7478 921- 151 Fax: (011) 49 7478 921- 400
DATE PREPARED:	February 08, 2008
DEVICE TRADE NAME:	RotaFlow Centrifugal Pump with Bioline Coating
COMMON/USUAL NAME	Centrifugal Pump
CLASSIFICATION NAME	Pump, Blood, Non-roller type, Cardiopulmonary
PREDICATE DEVICES OR LEGALLY MARKETED DEVICES	RotaFlow Centrifugal Pump with Safeline Coating Quadrox D Diffusion Membrane Oxygenator with Bioline Coating

DEVICE DESCRIPTION / INDICATONS FOR USE STATEMENT

The RotaFlow Centrifugal Pump is is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

The Bioline Coating improves the physical surface properties of products for the extracorporeal circulation system.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The RotaFlow Centrifugal Pump with Bioline Coating is identical to the RotaFlow Centrifugal Pump with Safeline Coating with the only exceception that the RotaFlow Centrifugal Pump with Bioline Coating has been coated with Bioline. The Bioline Coating is the same as with the Quadrox D Diffusion Membrane Oxygenator with Bioline. Besides this difference the both RotaFlow Centrifugal Pumps are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Evaluation on safety and effectiveness was executed to demonstrate that the RotaFlow Centrifugal Pump with Bioline Coating described in this submission is substantially equivalent to the RotaFlow Centrifugal Pump with Safeline Coating as a centrifugal pump and to the Quadrox D Diffusion Membrane Oxygenator with Bioline Coating with regards to the Bioline Coating.

The following areas have been evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the RotaFlow Centrifugal Pump with Bioline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.